

EXHIBIT ~~11~~**510(K) SUMMARY**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K063856.

**1. Submitter's Identification:**

Essential Dental Systems, Inc.  
89 Leuning Street  
South Hackensack, NJ 07606

Date Summary Prepared: December 27, 2006

Contact: Mr. Brian Rasimick

**2. Name of the Device:**

EZ-Fill® Xpress Epoxy Root Canal Cement System

**3. Predicate Device Information:**

1. The Bi-Directional Spiral & Epoxy Root Canal Cement System, K# 992727, MDS, New York, NY

2. AH-Plus™ Root Canal Sealer, K# 960548, Dentsply International, York, PA

**4. Device Description:**

The device description is identical to that of the predicate device, Bi-directional Spiral & Epoxy Root Canal Cement System:

The EZ-Fill® Xpress Epoxy Root Canal Cement System is an obturation system for filling straight and minimally curved canals. The bi-directional spiral (cement carrier that fully coats the canal, but prevents excess cement from exiting apically) and epoxy root canal cement, combined with a single point technique, creates a seal equivalent to lateral condensation and thermoplastic gutta percha.

The contents of the kit are identical except that '2 - Dual Chambered Syringes containing 9.5 gm of root canal sealer' and '20 - Mixing Tips' replace the '7.5 gm -

Epoxy Root Canal Cement Gel, 8.0 gm – Powder (Epoxy Root Canal Cement), and 1 Measuring Scoop.’ The full list of contents is as follows:

- 4 – Color Coded to ISO Size 25 Bi-Directional Spirals (1 – 21mm length and 3 – 25 mm length)
- 2 – Dual Chambered Syringes containing 9.5 gm root canal sealer
- 20 – Mixing Tips

**5. Intended Use:**

The EZ-Fill® Xpress Epoxy Root Canal Cement System is indicated for permanent sealing of root canals following established endodontic procedures.

**6. Comparison to Predicate Devices:**

The subject device is a derivative of EZ-Fill®(component of the Bi-Directional Spiral & Epoxy Root Canal Cement System). Both the EZ-Fill® and subject device are two-component epoxy/amine systems that use bismuth oxide as the primary radiopacifying agent. Both are applied to the tooth using the Bi-Directional spiral and used in conjunction with the same auxiliary materials in the root canal (i.e. gutta percha points).

Unlike traditional EZ-Fill®, the subject device is a gel/gel system rather than a powder/gel system. This is due to a change in the amine curing agent. The gel/gel formulation of the subject device is delivered by a dual chambered syringe as is the gel/gel formulation of AH-Plus™ Jet.

The subject device does not contain silver. Instead, the subject device contains three ingredients found in AH-Plus™ endodontic sealer - zirconium dioxide, fumed silica, and iron oxide.

**7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

Bench Testing performed on the EZ-Fill® Xpress Epoxy Root Canal Cement System meet/exceed ADA Specification No.57 (Dental Root Canal Filling Material) and ISO 6876 (Endodontic Filling Materials) including physical properties such as flow, film thickness, dimensional stability, solubility and disintegration. Bi-Directional Spiral (reverse spiral drill) dimensional inspections are checked to meet all required specifications

Biocompatibility literature supplied with this 510(k) submission along with Material Safety Data Sheets, has shown that the EZ-Fill® Xpress Epoxy Root

Canal System material, as well as the material contained in the predicate devices, do not raise any new safety/biocompatibility concerns.

**8. Discussion of Clinical Tests Performed:**

Not Applicable.

**9. Conclusions:**

The EZ-Fill® Xpress Epoxy Root Canal Cement System has the same intended use and similar technological characteristics as the predicate devices. Moreover, bench testing contained in this submission and clinical literature supplied demonstrate that any differences in their material formulations do not raise any new questions as to safety or effectiveness. Thus, the EZ-Fill® Xpress Epoxy Root Canal Cement System is substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Essential Dental Systems, Incorporated  
C/O Ms. Susan D. Goldstein-Falk  
MDI Consultants, Incorporated  
55 Northern Boulevard, Suite 200  
Great Neck, New York 11021

FEB 6 2007

Re: K063856

Trade/Device Name: EZ-Fill® Xpress Epoxy Root Canal Cement System  
Regulation Number: 21 CFR 872.3820  
Regulation Name: Root Canal Filling Resin  
Regulatory Class: II  
Product Code: KIF  
Dated: December 27, 2006  
Received: December 28, 2006

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

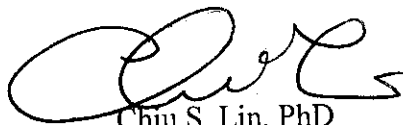
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Chiu S. Lin', with a stylized flourish at the end.

Chiu S. Lin, PhD

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

Page 1 of 1

510(k) Number (if known): 12063856

Device Name: The EZ-Fill® Xpress Epoxy Root Canal Cement System

Indications For Use:

The EZ-Fill® Xpress Epoxy Root Canal Cement System is indicated for permanent sealing of root canals following established endodontic procedures.

Prescription Use x  
Use \_\_\_\_\_

(Per 21 CFR 801 Subpart D)

Over-The Counter

OR

(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

*Susan Reese*

Special Agent (FDA)  
Division of Anesthetic, General Hospital,  
Control, Dental Devices

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